United States
Department of
Agriculture

Food Safety
and Inspection
Service

Compilation of Meat and Poultry Inspection Issuances

November 4, 1985 thru
February 26, 1986

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The period covered in this Issuance is November 4, 1985, to February 26, 1986.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 88-85 | 12/3/85

MP FORM 423 "SUBMISSION AND APPROVAL OF PLANS AND SPECIFICATIONS"

The purpose of this Notice is to inform inspection personnel of the applicable form to use when submitting blueprints for approval.

It has been noted that, in some instances, the old form, MP Form 423 dated 1/83, is continuing to be used. That form is obsolete and should no longer be used and, therefore, any excess supply that is on hand should be destroyed.

When submitting blueprints to MPITS/FESD, use the updated MP Form 423 dated 11/83. It is essential that all blocks on this form be completed. Special instructions outlined on the form should be followed by the IIC in completing the fifth copy of the form prior to submission to MPITS/FESD.

Deputy Administrator
Meat and Poultry Inspection Operations

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, ABB, TRA, R&E, Import Offices	4-15-86	MPITS/FESD

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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 89-85 | 12-4-85

QUARTERLY SUBMISSION OF MP FORM 404

Fiscal year 1985 closed with the quarter ending October 1, 1985. Submission of quarterly reports on MP 404 for fiscal year 1986 will include data for the following periods:

October 1, 1985 - December 31, 1985
January 1, 1986 - March 31, 1986
April 1, 1986 - June 30, 1986
July 1, 1986 - September 30, 1986

At the end of each quarterly period, plant management provides the inspector with the completed MP Form 404, in triplicate. The inspector, after auditing and approving the report, will mail the original as soon as possible, but no later than the 15th calendar day following the end of the quarter to:

Data Services Center
Meat and Poultry Inspection, FSIS
U.S. Department of Agriculture
210 Walnut Street, Room 791
Des Moines, IA 50309

Deputy Administrator
Meat and Poultry Inspection Operations

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, R&E, TRA, ABB	6-4-86	FSIS/MPITS/Processed Products Inspection Division

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE

91-85 | 12-10-85

INVENTORY OF CURRENT INSPECTION RELATED ISSUANCES

Since January 1984, all new inspection related instructions have been issued as FSIS Directives (in the 5000 - 12000 Series) or FSIS Notices. These materials are one part of the Agency's comprehensive issuance system; the other principal part of which is the administrative-related FSIS Directives (1000 - 4000 Series) and FSIS Notices.

The Agency has now inventoried all pre-1984 program-related issuances - MPI Directives, MPI Bulletins, FSIS Directives and the MPI Manual. A comprehensive review is being undertaken of all these materials and, over the next few years, the pre-1984 issuances will be incorporated into new FSIS Directives.

During this transition period extra effort will be made to provide clear, concise maintenance instructions to users. Also, this inventory will be updated and published on a semi-annual basis.

The MPI Manual will remain in effect and, as necessary, be updated EXCEPT for sections expressly cancelled normally by a superseding FSIS Directive.

The attached inventory is a comprehensive listing of current inspection related FSIS Directives and FSIS Notices and the still-effective MPI Directives and MPI Bulletins. A list of the MPI Manual parts that have been cancelled since 1984 is also included in this inventory. For recordkeeping purposes, this inventory should be filed in the front of the issuance binder until superseded by an updated inventory to be published semi-annually. Included in this Notice are pages marked FSIS Directives, FSIS Notices and MPI Manual Deletions for use in maintaining a current list of issuances. As new issuances are published, write that issuance number, and subject on the respective page and when the updated inventory is published, destroy this Notice.

This document listing all effective issuances provides all FSIS personnel the opportunity to "clean house." All outdated material not listed can and should be discarded. It is suggested that users of the MPI Manual should cross out deleted sections and, where appropriate, note the FSIS Directive or other issuance that superseded that particular section.

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB	6-10-86	PP/RDU

If copies are needed of any issuance listed in this notice, please contact the Regional Office or, for Washington-based persons, contact the Printing and Distribution Branch, (202) 447-4661.

Administrator

INVENTORY OF INSPECTION RELATED ISSUANCES

Policy and Planning Staff
Policy Office
Regulations Development Unit

Current As Of 10/21/85

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MPI MANUAL DELETIONS

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Section 17.13(j)(1)	§ 319.702 - MPI Regulations
Section 20.4	Obsolete - handled by Meat Grading Branch, AMS
Section 20.5	Obsolete - handled by Meat Grading Branch, AMS
Section 22.1	FSIS Directive 9020.1 dated 5/15/84
Sections 22.2 22.3 22.6	FSIS Directive 9040.1 dated 5/15/85
Sections 22.4 22.5 22.7	FSIS Directive 9060.4 dated 11/20/84
Section 22.17	FSIS Directive 9080.1 dated 9/6/84
Section 22.63	FSIS Directive 9355.1 dated 6/12/85
Section 22.77	FSIS Directive 9430.1 dated 10/10/85

FSIS DIRECTIVES

Number/Date	Subject

FSIS NOTICES

Number/Date	Subject

MPI MANUAL DELETIONS

Part	Superseded by

MPI MANUAL DELETIONS
(Continued)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 92-85 | 12-12-85

PARTIALLY COOKED, COMMINUTED, UNCURED PRODUCTS

I. PURPOSE

This notice identifies certain heat-treated products which may require processing or labeling changes. It contains time and temperature combinations that allow the Agency to conclude that the product is safe to eat without further heating; states what instructions, in the alternative, can be on the label; and requests information concerning some of the processes and labels of manufacturers who produce these products. This information will be used in taking actions to minimize the opportunity for such products to be carriers of food-borne pathogens.

II. IDENTIFICATION OF PRODUCT

This notice applies to all red meat items and to battered and breaded poultry items which are heated, uncured, and comminuted (formed or unformed). Examples of such product are: charbroiled meat patties, meat crumbles, meat loaves, meat nuggets, comminuted barbecued meat, breaded poultry nuggets, and battered and breaded poultry patties.

III. IDENTIFICATION OF PROCESSES

This notice affects heat processing procedures in which the finished product may appear to be fully cooked to the ultimate consumer. These processes involve all forms of heat treatment, including heat application of "char" marks, pre-cooking, semi-cooking, partially cooking, barbecuing, and "setting" batter.

IV. PROCESSING PROCEDURE AND LABEL MODIFICATIONS

The Inspectors-In-Charge (IIC's) are to review the process of all products affected by this notice and take action if appropriate by March 31, 1986. The process for each product shall be compared with the following time and temperature table:

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB	July 1, 1986	MPITS/PPID

TABLE OF TIME/TEMPERATURE COMBINATIONS FOR HEATED, UNCURED, COMMINUTED RED MEAT PRODUCT (FORMED OR UNFORMED) AND FOR HEATED, UNCURED, COMMINUTED, BATTERED AND BREADED POULTRY PRODUCT

Minimum Internal Temperature		Minimum Processing Time In Minutes After Minimum Internal Temperature Is Reached
Degrees Centigrade	Degrees Fahrenheit	
66.1 and above	151 and above	1
64.4	148	2
63.2	146	3
62.8	145	4
62.2	144	5

The status of the plant's process and the need for future action can be determined by comparing the following situations to the process and/or label application form. If you have any questions regarding any of the situations or interpretations of this notice, refer to Section V for the contact office. The following situations, in order, define the action to be taken by the IIC:

A. Patty or Other Partially Cooked Product Covered by this Notice. If the process for each product **is** as rigorous as the table, no further action relative to the process or label is required. Disregard the remainder of this notice.

If the process for each product **is not** as rigorous as the table but each product's labeling **does** contain instructions to the end-user to further cook the product before consumption, no further action is required. Disregard the remainder of this notice.

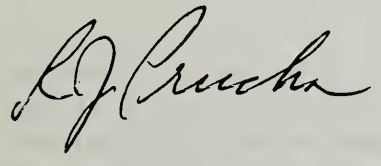
B. Red Meat/Patty or Battered and Breaded Poultry Patty Covered by this Notice. If the process **is not** as rigorous as the table and the labeling **does not** contain instructions to the end-user to further cook the product before consumption, **but** the manufacturer is willing to voluntarily modify the processing procedure and/or the labeling instructions for further cooking within a reasonable period of time, then document and implement the modifications. No further action is required. Disregard the remainder of this notice.

If the process **is not** as rigorous as the table, the label **does not** contain instructions to the end-user to further cook the product before consumption, **and** the manufacturer **is not** willing or is unable to modify the processing procedure and/or the labeling instructions to clearly indicate further cooking, then send the processing procedures (time/temperature) and label approval number through the Regional Office to Bill F. Dennis, Processed Products Inspection Division, MPITS, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

C. Partially Cooked Product, Other than Patty, Covered by this Notice. If the process **is not** as rigorous as the table and the label **does not** contain instructions to the end-user to further cook the product before consumption, do not seek any changes in the processing procedure or the labeling but send the processing procedures (time/temperature) and label approval number through the Regional Office to Bill F. Dennis (see address above).

V. QUESTIONS REGARDING THIS NOTICE

Should there be any questions regarding this notice, contact the Regional Office.



Deputy Administrator
Meat and Poultry Inspection Operations

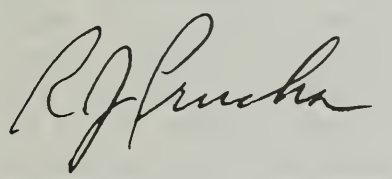
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 3-86 | 1-13-86

WEEKLY LIVESTOCK SLAUGHTER REPORT LS-149

The Weekly Livestock Slaughter program has been changed to incorporate dairy cows as a permanent and integral part of the reporting form. The Weekly Livestock Slaughter Report LS-149 has been revised to separate total cows into two classes; dairy cows and other cows. Use of the supplemental LS-149 to report weekly diary cow slaughter will no longer be needed. Weight data will continue to be requested for all cows (beef and dairy combined) as reported on earlier versions of the LS-149 form.

An initial supply of the new Weekly Livestock Slaughter LS-149 forms is being mailed to each slaughter plant by the Statistical Reporting Service. The new revised LS-149 have been mailed and should have been received at your plant. Please begin to use these forms immediately. If additional forms are needed, enclose a note in the envelope with the weekly LS-149 report or call 202-447-6880. Any previously issued Weekly Livestock Slaughter Report Forms (LS-149) are to be destroyed along with The Dairy Cow Slaughter Report LS-149 Supplement.



Deputy Administrator
Meat and Poultry Inspection Operations

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
MPI Headquarters and Field Offices, T/A Meat Slaughter Plants, T/A Meat Slaughter plant management, All Meat Slaughter Inspection Personnel, All Meat Slaughter Plant Management, ComplianceOffices	1-13-87	MPIO/RO

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 5-86 | 1-31-86

LEPTOSPIROSIS SURVEY

The Food Safety and Inspection Service (FSIS) is cooperating with Veterinary Services, APHIS (VS) in conducting a survey to determine the prevalence of **Leptospira interrogans serovars** in mature cattle in the conterminous United States. A total of 5,000 samples will be collected from FSIS-inspected livestock slaughter establishments during a period of 1 year beginning February 1, 1986. Inspectors in charge at such plants will ensure that samples are taken and submitted as set forth in this notice.

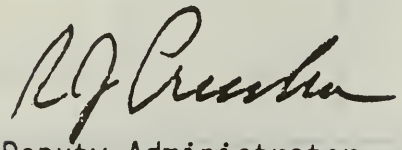
Collection and shipping materials will be mailed weekly to selected plants from National Veterinary Services Lab (NVSL) in Ames, Iowa. A computerized system will be used to direct random sampling in proportion to the slaughter rate of each plant and the system will also designate dates and times of sampling. A form will be included in each shipping container also giving instructions for specimen collection and shipment.

A sample will consist of one section of kidney, one cubic centimeter in size, and one blood sample from the same animal. Insert the modified syringe into the kidney to a depth of one inch and rotate it to cut the tissue loose. Use a different sterile syringe for each sample. Pry out the tissue with the sharp tip of the syringe and place the tissue in the plastic bottle containing liquid. Take a blood sample from the same animal in the blood collection tube that has the same number as the bottle in which the tissue was placed. Fill the blood tube within one inch of the top. Record the sample number, date of collection, backtag/ear tag number, sex, **(cow or bull,)** state of origin, and estimated age. Refrigerate the samples immediately after collection.

On each of the dates identified by NVSL, select one animal to be sampled at random, without regard for the presence or absence of signs of disease. Sample **cows and bulls only**. Do not sample steers, heifers, or calves. Collect kidney tissue and blood from each animal that is to be sampled. Samples should be mailed from the plants in styrofoam containers with ice packs, using the mailing label that was in your material from NVSL, as soon as possible after collection. If delays are necessary before shipment, the specimens must be kept under refrigeration.

DISTRIBUTION:	**NOTICE EXPIRES:**	**OPI:**
All MPI Offices, T/A Insp., Plant Mgmt, T/S Plant Mgmt, SCI and Compliance Offices, ABB TRA, R&E, Import Offices, VS and NVSL by MPIO	August 1, 1986	MPIO/RO

Questions regarding this sampling program should be directed to Dr. H. C. Hairston, (202) 447-3697, MPIO, Regional Operations, Washington, DC, through the Regional Office.



Deputy Administrator
Meat and Poultry Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 6-86 | 2-20-86

SULFITING AGENTS IN MEAT AND POULTRY FOOD PRODUCTS

I. PURPOSE

This notice provides information on common sulfiting agents used in or on foods as formulation ingredients; it explains how their presence may be determined; and, it specifies how they should be labeled in meat and poultry finished products. It advises Inspectors-in-charge that product label modifications may be necessary to denote the presence of sulfiting agents, and explains conditions for use of non-complying labels during an interim period until the label can be changed.

II. SCOPE

This notice applies to all USDA-inspected meat and poultry food products.

III. IDENTIFICATION OF SULFITING AGENTS

Federal meat inspection regulations prohibit the direct addition of sulfiting agents to meat food products (9 CFR 318.7(d)(2)), but sulfiting agents may be present in or on processed fruits or vegetables used as ingredients of those products. Sulfiting agents which may be present as components of formulation ingredients in meat or poultry products include sulfur dioxide, sodium sulfite, potassium bisulfite, potassium metabisulfite, sodium bisulfite, and sodium metabisulfite.

IV. COMPLIANCE PROCEDURE AND LABEL MODIFICATION

A. Inspectors-in-Charge are to review the formulation and raw material components of all finished products produced at their establishment for the presence of sulfiting agents. Formulation components, such as fruits and vegetables, should be checked against supplier and raw material labels as well as supplier specifications for the presence of sulfiting agents.

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All Washington Offices, Field Offices, Inspection Offices, and Plant Mgmt.	2-20-87	MPIO

B. Action will be taken according to which of the following conditions are found to exist:

1. **Condition 1.** Sulfiting agents **are not used** in or on one or more ingredient components of finished meat or poultry food products. **Action.** No further action relative to the label is required.

2. **Condition 2.** Sulfiting agents **are used** in or on one or more ingredient components of finished meat or poultry food products, and the sulfiting agent(s) **are declared** in the ingredient statement of the finished product. **Action.** No further action relative to the label is required.

3. **Condition 3.** Sulfiting agents **are used** in or on one or more ingredient components of finished meat or poultry food products and the sulfiting agent(s) **are not declared** in the ingredient statement of the finished product label. **Action.** The label must be resubmitted to the Standards and Labeling Division, MPITS, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250 for six (6) month temporary approval. Advise plant management of the action taken and inform them that product labels must be corrected no later than the temporary label approval expiration date. No extensions beyond that date will be granted under any circumstances due to health risks posed by sulfiting agents to certain individuals who are susceptible to severe reactions from consumption of these substances.

V. QUESTIONS REGARDING THIS NOTICE

Direct any questions regarding this notice to the Regional Office.

Deputy Administrator
Meat and Poultry Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 7-86 | 2-6-86

REDUCTION IN SAMPLING

The Food Safety and Inspection Service (FSIS) efforts to decrease Fiscal Year 1986 expenditures as much as possible include reductions in a number of Science activities. Dr. Houston's memorandum of November 15, 1985, imposed restrictions in the funding for certain contracts. One of these restrictions imposes a 10 percent cut in contract funds for analyses conducted by the FSIS contract laboratories, California, Kentucky and Webb Foodlab. In order to achieve this cost reduction, it will be necessary to curtail sample submissions to the FSIS contract laboratories by a corresponding 10 percent.

Inspectors in Charge of all meat and poultry processing assignments are directed to reduce sample submissions by 10 percent, effective immediately. Inspectors in Charge shall use their discretion to determine how to apply this reduction.

Inspectors in Charge should not reduce the following special samplings: PFF computer-requested samples, investigative samples or verification samples.

Deputy Administrator
Meat and Poultry Inspection Operations

DISTRIBUTION: Poultry Processing Inspectors, Red Meat Processing Inspectors	**NOTICE EXPIRES:** 2-6-87	**OPI:** SCI/FSLD

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D. C.

FSIS NOTICE | 11-86 | 2-14-86

FEDERAL TRIANGLE BRAND FOR BUFFALO

I. PURPOSE

This notice provides information to FSIS personnel and the regulated industry concerning the replacement of the circular red meat brand with the new triangular buffalo brand for marking inspected and passed buffalo and buffalo meat food products.

II. EFFECTIVE DATE

Beginning June 24, 1986, all buffalo and buffalo meat food products that are federally inspected and passed must be marked with the new triangular brand. Federal establishments that have been approved for buffalo inspection may continue to use the Federal circular red meat brand for marking inspected and passed buffalo and buffalo meat food products until June 24, 1986.

Deputy Administrator
Meat and Poultry Inspection Operations

DISTRIBUTION:	NOTICE EXPIRES:	OPI:
All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, ABB, TRA, R&E	06/24/86	RO, Meat and Poultry Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

☒ DIRECTIVE
☐ REVISION
☐ AMENDMENT
☐ OTHER

FSIS DIRECTIVE 6810.2, MARKING CARCASSES AND PRODUCTS (MEAT)	6810.2	1/2/86

I. PURPOSE

This document transmits FSIS Directive 6810.2 and provides instructions to users regarding deletion of sections of the Meat and Poultry Inspection Manual.

II. INSTRUCTIONS

The attached directive supersedes sections 16.6, 16.7, and 16.11 of the Meat and Poultry Inspection Manual. Please cross out these sections in your Manual and note therein that the current instructions are contained in FSIS Directive 6810.2.

III. CANCELLATION

This change transmittal is cancelled when contents have been filed and the Meat and Poultry Inspection Manual maintenance instructions outlined above have been completed.

Deputy Administrator
Meat and Poultry Inspection Operations

Attachment
FSIS Directive 6810.2

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance, R&E, Import Offices, TRA, ABB

OPI: MPITS/Standards and Labeling Division

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

6810.2 | 1/2/86

MARKING CARCASSES AND PRODUCTS (MEAT)

I. PURPOSE

This Directive provides procedures for branding carcasses, parts of carcasses, and products.

II. CANCELLATION

This Directive supersedes sections 16.6, 16.7, and 16.11 of the Meat and Poultry Inspection Manual.

III. [RESERVED]

IV. REFERENCES

Sections 311.22, 311.23, 312.2, and 312.3, and Part 316 of the Federal Meat Inspection Regulations

V. PROCEDURES

A. Carcass Marking.

1. Each half carcass shall be legibly marked "U.S. Inspected and Passed" after inspection is completed.

2. Inspectors apply brand imprints on carcasses as required to assure the brand will be visible. Inspectors have discretion as to location and number of brand imprints applied to carcasses. However, a minimum of one brand imprint is required on each half carcass.

3. Shrouded carcasses.

a. Shrouding carcasses should not cause brands to become smeared or illegible.

b. If shrouded carcasses are shipped from an official plant, additional brands shall be applied to carcasses if necessary to ensure they are clearly visible without shroud removal.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance, R&E, Import Offices, TRA, ABB

OPI: MPITS/Standards and Labeling Division

4. Carcasses placed in bags or other coverings shall bear prominent and legible official inspection legends on the outer covering. (See section 316.13 of regulations for exceptions.)

5. Cysticercosis beef carcasses passed subject to retention under refrigeration, in accordance with section 311.23 of the meat inspection regulations, may be marked "U.S. Inspected and Passed" just before being placed into a freezing compartment under government lock or seal.

6. Papain injected carcasses shall be marked "Tendered with Papain" by continuous roller brand applied over the round, loin, rib, neck, chuck, foreshank, flank, plate, brisket.

7. "Hide-on" calf carcasses must be marked "U.S. Inspected and Passed" at the originating establishment. Carcasses shipped to other plants must be marked with the receiving establishment number and inspection legend after hide removal.

B. Product Marking.

1. Meat Cuts from carcasses marked at another establishment shall be branded with the official inspection legend and establishment number where cut.

2. "Tender" or words of similar meaning may be branded on pork products heated to at least 140° F. internal temperature.

3. "Ready-to-Eat", "Cooked", "Fully Cooked", "Thoroughly Cooked", or "Ready-to-Serve".

a. These are terms that may be marked on heated and smoked products provided the product shows cooked characteristics such as:

(1) Partial meat separation from bone,

(2) Easy tissue separation, and

(3) Cooked color, texture, and flavor.

This usually requires a minimum internal temperature of 148° F.

b. When marking devices are submitted for approval of these terms, the application should contain complete processing procedures and internal temperatures attained.

4. "Cereal Added", "Nonfat Dry Milk Added", Artificially Colored" and similar qualifying statements shall be marked on product or on marking devices attached to product in the order that the ingredients are added during processing.

C. Horse or Other Equine Marking.

1. Horse or other equine carcasses and products shall be marked with the inspection device specified in section 312.3 of the meat inspection regulations.

2. Chunks or large pieces of product packed in properly labeled shipping containers shall be individually marked, unless shipped from one official establishment to another under government lock or seal.

3. Each equine tenderloin shall be marked before shipment.

4. The official inspection legend and establishment number may be applied to the outer cloth covering of horse or other equine carcass or parts with the 2½ rubber brand, provided the applicable term such as "Horse Meat" or "Equine Meat Product" is placed contiguous to each brand in letters at least 1 inch high.

5. Green ink shall be used in marking carcasses and parts. The following formula has given satisfactory results:

FD & C Green No. 3	3½%
Dextrose	3%
Water	16%
Edible Shellac	2%
95% Ethyl Alcohol	75%

Deputy Administrator
Meat and Poultry Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

7110.1 | 2-26-86

GUIDELINES FOR SPECIFIED CUTS OF POULTRY

I. PURPOSE

This directive provides guidance concerning the manner of cut for specific labeling of cut-up poultry parts, and adds specificity and clarity to the regulation cited below.

II. RESERVED

III. RESERVED

IV. REFERENCES

Sections 381.170(b), Meat and Poultry Inspection Regulations.

V. RESERVED

VI. POLICY

Section 381.170(b) provides standards which specify the requirements for certain cuts of poultry.

VII. PROCEDURES

The following are procedures to clarify and assure compliance with the provisions of the regulations regarding cut-up poultry parts. These procedures are to be used in conjunction with section 381.170(b) of the poultry regulations.

A. **Proper cut of thighs, drumsticks and wings.** Thighs, drumsticks, and wings should be separated from other parts with clean cuts through connecting joints. These parts may still be considered properly cut if the medullary cavity (marrow) of the bone shaft is not exposed. If the part is improperly cut, both ends shall be labeled portions of drumstick, thigh, or wing, unless the parts are acceptable for, and identified with, an official USDA Grade Mark. For example, if the bone of a part is cut short (i.e., medullary cavity exposed), but all of the meat yield associated with that part is not materially affected, then the part may qualify for a grade other than "A" grade.

DISTRIBUTION: All MPI Offices, T/A Poultry Inspectors, Poultry Plant Management, T/A Poultry Plant Management, Science and Compliance Offices, ABB, TRA, R&E, Import Offices

OPI: Meat and Poultry Inspection Operations

B. Patella (kneebone). The patella (kneebone) may be included on either the drumstick or thigh.

C. Skin and Fat. Skin or fat not ordinarily associated with a part may not be included unless stated on the label.

D. Thighs. The regulation states that thighs may include pelvic meat but shall not include the pelvic bones. Thighs may also include abdominal meat (flank meat) but shall not include rib bones.

E. Legs. The regulation states that legs may include pelvic meat but shall not include the pelvic bones. Legs may also include abdominal meat (flank meat) but shall not include rib bones.

F. Halves. The regulation states that a poultry carcass is cut so as to produce approximately equal right and left sides. The cut must be made so that portions of the backbone remain on both halves, and the cut may be no more than ¼ inch from the sternum (breastbone).

G. Leg quarter. The regulation states that a leg quarter consists of a poultry thigh and drumstick with approximately ½ of the associated back porton attached. A leg quarter may also include attached abdominal fat and up to two ribs.

H. Leg quarters with back portion. This is a leg quarter with a complete or entire rear back portion attached. In order for this part to be properly labeled, the back portion must have all associated meat and skin. If the meat and skin are missing, this cut should be labeled as leg quarter with stripped back portion.

I. Breasts. Abdominal muscle (flank meat) shall not be included except for occasional small pieces. Skin or fat from other parts may not be included. The end of the humerus may be included on the breast if the medullary cavity (marrow) of the bone shaft is not exposed. If the medullary cavity is exposed, then a portion of wing bone is attached and this cut must be labeled as breast with portion of wing bone.

J. Breast with ribs. Abdominal muscle (flank meat) remaining on the breast shall not extend beyond the midline of the internal side of the sternum (breastbone) when folded inward from its natural attachment to the breast. If this abdominal muscle has been partially cut at its natural attachment to the breast, then the cut edge is to be approximated before folding. Skin or fat from other parts is not allowed. The end of the humerus may be included on the breast if the medullary cavity (marrow) of the bone shaft is not exposed. If the medullary cavity of the humerus is exposed, then a portion of wing bone is attached and this cut must be labeled as breast with ribs with portion of wing bone.

Deputy Administrator
Meat and Poultry Inspection Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9205.1
REVISION 1

1/2/86

FRENCH LABELING REQUIREMENTS

I. PURPOSE

The purpose of this directive is to update labeling information required by France.

II. CANCELLATION

FSIS Directive 9205.1, dated 10/3/85.

III. [RESERVED]

IV. REFERENCES

Section 22.35, Meat and Poultry Inspection Manual.

V. REQUIREMENT

French inspection officials require new information on labels of meat and poultry products for export to France effective December 21, 1985.

This information updates existing label requirements described in Section 22.35 of the Meat and Poultry Inspection Manual. Other requirements of Section 22.35 remain in effect.

VI. LABELING REQUIREMENTS

In addition to USDA mandatory labeling information, all packaged food products must bear labels printed in French (bilingual is acceptable) and show the following information:

A. **Bulk And Consumer-Size Packages.**

1. Name of product including the physical state of the product, e.g., frozen pork livers.

2. Net quantity in metric units.

DISTRIBUTION: All MPI Offices. T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: IP/ECD

3. Full name and address of producer, packager, or EEC-recognized importer.

4. Country of origin.

5. List of ingredients, if applicable.

6. Lot identification, if applicable.

7. Slaughter or freezing date for fresh/frozen product; production date for processed product. See Paragraphs C.2. and C.5.

8. Optimal date of utilization or expiration date, as applicable. See Paragraphs C.3. and C.4.

9. Storage instructions including a recommended storage temperature, e.g., "Keep frozen. Store at ____°C or less."

B. **Consumer-Size Packages.** When applicable, the following information should be shown in addition to that of Paragraph A:

1. Directions for use.

2. Directions for special storage.

C. **Marking of Dates.**

1. General date format. Dates must be:

a. Uncoded.

b. In the following sequence: day, month, year.

c. Written with the month spelled out or abbreviated to three letters.

2. Date format/stability. Use the following format for food products with a stability of:

a. Less than 3 months: Day/Month.

b. Between 3 and 18 months: Month/Year.

c. More than 18 months: Year.

3. The optimal date of utilization. The following terms are specified in French for use with product which is stable:

a. Less than 3 months:

"A consommer de preference avant **(Day/Month)**." (To be consumed preferably before **(Day/Month)**.

b. Between 3 and 18 months:

"A consommer de preference avant fin **(Month/Year)**. (To be consumed preferably before the end of **(Month/Year)**.

c. More than 18 months:

"A consommer de preference avant fin **(Year)**." (To be consumed preferably before the end of **(Year)**.

4. The expiration date. The following products must bear an expiration date:

a. Those products perishable within a 6 week period.

b. Those products containing regulated materials for which an expiration date has been set. Fresh/frozen meats or poultry are not included in this group.

5. Production date. The production date may be the date of production or the date of packaging. The date may be indicated in one of the following ways:

a. Day/Month/Year.

b. A group of 4 or 5 numbers indicating the last number or the last 2 numbers of the year and 3 numbers from 001 to 366 indicating the day of production in the year.

c. Code dates may be used on certain retail products such as canned goods. Code information:

(1). Must be provided to the French Ministry of Agriculture prior to any sales of product in France.

(2). Should be directed to: la Direction de la Consommation et de la Repression des Fraudes, 13, rue Saint-Georges, 75436 PARIS CEDEX 09.

(3). Frozen products are not eligible to bear coded dates.

This information will be included in the comprehensive FSIS Directive for France to be issued at a later date.

Deputy Administrator
Meat and Poultry Inspection
Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9455.1 | 1/2/86

SPANISH LABELING REQUIREMENTS INCLUDING THE CANARY ISLANDS

I. PURPOSE

The purpose of this directive is to inform inspectors-in-charge and inspectors of requirements by Spanish officials.

II. CANCELLATIONS

FSIS Notice 72-84, dated 10/23/84.

III. RESERVED

IV. REFERENCE

MPI Manual 22.79

V. REQUIREMENT

Spanish inspection officials have informed FSIS that all packaged food products must bear labels printed in Spanish. Those labels must show the following information in addition to the requirements in section 22.79 of the MPI Manual.

A. Shipping Containers

1. Full name, address, and registration number of Spanish importer.

2. Weight in metric units.

3. Slaughter or freezing date for fresh/frozen product; production date for processed product.

4. Expiration or minimum duration date, as applicable, from paragraphs C and D of this directive.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, Science and Compliance Offices, T/A Plant Management, R&E, Import Offices, TRA, ABB

OPI: PP/RDU

B. Consumer Size Packages

1. Name of product.

2. List of ingredients.

3. Weight in metric units.

4. Directions for food preservation, if applicable.

5. Name and address of manufacturer, packer, or importer.

6. Identification of lot.

7. Country of origin.

8. Expiration or minimum duration date, as applicable, from paragraphs C and D of this notice.

C. Marking of Dates

1. The minimum duration date. For food products with a duration of:

a. Under 3 months, the following statement must be used: "To be consumed preferably prior to (day/month/year)".

b. Three to 18 months, use the following statement: "To be consumed preferably prior to **(month/year)**". This statement should be used for most fresh/frozen meat/poultry product.

c. More than 18 months, use the following statement: "To be consumed preferably before the end of **(year)**".

2. The expiration date. For food products which are microbiologically perishable within a short period of time, the expiration date must be shown as follows: "Expiration Date **(day/month/year)**".

D. Printing of Dates - All dates involved must be shown in the following manner:

1. The day, by the applicable digits(s).

2. The month, by its name or by the first three letters of the name.

3. The year, by its four digits or by its last two digits.

4. The order of dates used must be: day/month/year.

This information will be included in a comprehensive FSIS Directive on exports to Spain to be published at a later date.

Deputy Administrator
Meat and Poultry Inspection
Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9620.1 | 1-23-86

INCUBATION REQUIREMENTS FOR SHELF-STABLE, HEAT-PROCESSED IMPORTED MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive contains the requirements for the incubation of shelf-stable, heat-processed imported meat and poultry products and provides procedures and requirements for shipping these products before incubation results are obtained.

II. CANCELLATION (RESERVED)

III. (RESERVED)

IV. REFERENCES

A. Sections 318.11(i) and 327.6 of the Federal meat inspection regulations, and sections 381.149(g) and 381.199(a)(1)-(4) of the poultry products inspection regulations.

B. Sections 18.47, 27.12, and 27.16 of the Meat and Poultry Inspection Manual.

V. DEFINITIONS AND FORMS

The following terms used in this directive are defined as follows:

Importer: The person, company or brokerage firm applying for inspection of imported meat and poultry products, as identified in Section A.1. of the MP Form 410.

MP Form 410: Import Inspection Application and Report.

Warehouse: A storage location where retail trade in meat and poultry products is not conducted.

Retail: Trade directly to consumers.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: Import Inspection Division, IP

VI. GENERAL REQUIREMENTS

A. **Products to be Incubated.** Incubation requirements as set forth in section 327.6 of the regulations apply to all thermally processed product packed in hermetically sealed containers that are intended to be shelf-stable under normal nonrefrigerated conditions.

B. **Purpose of Incubation**

The purpose of incubation is to provide increased assurance of the safety and stability of shelf-stable canned product.

C. **Sampling.** The Automated Import Information System (AIIS) may assign incubation to any lot of imported shelf-stable canned product based on a history of producing plant performance. Inspectors may choose to sample lots not assigned incubation by the AIIS when they have reason to suspect any problems. The random numbers for sampling the lot shall be drawn from the AIIS after any presorting of transportation-damaged cans or immediate containers by the importer. Using those random numbers, the inspector shall select 24 sample units from the lot for incubation.

D. **Temperature, Time and Equipment Requirements**

1. Incubation of sample units shall be in accordance with sections 318.11(i)(4), 327.6(l), and 381.149(g)(1) of the regulations; and sections 18.47(b)(1) and 27.16(c) and (e) of the Meat and Poultry Inspection Manual.

2. The inspector will check the temperature and samples daily, if possible, but at least twice during the 10-day cycle.

E. **Facilities**

The necessary incubation facilities shall be provided by the importer as required by section 327.6(e) of the regulations.

F. **Security.** When in use, the inspector shall keep the incubator and incubating samples under lock or under his or her personal supervision at all times.

G. **Records.** The inspector shall keep records which include the number of the MP 410, lot numbers of all samples in the incubator, code identification of all samples, the date the samples were placed in the incubator, the date the cans or immediate containers ar to be taken out, the dates on which the temperature was checked, and the cur ent lot status.

VII. APPLICATION FOR PRIOR SHIPMENT APPROVAL

A. Permission to move the product before the incubation results are received is a privilege granted to an importer, not to producing establishments. The importer must request and be granted permission in writing by the Import Field Office (IFO) Supervisor at each Import Field Office he/she deals with.

B. The letter of application must include the following details:

1. How and to which warehouses product might be transported and how control of the product will be maintained.

2. Guarantees that the product will not be distributed to retail points and will be kept intact so that it may be retrieved if a recall is necessary.

3. A description of the retrieval procedures.

C. Permission to ship product before incubation ends may be granted on a case-by-case basis to importers.

D. The written permission of the IFO Supervisor will take the form of a handwritten notation "Approved" on the letter of application and must show the IFO Supervisor's signature and a date. A copy of the letter with the approval notation will be kept on file in the IFO. Permission must be renewed annually.

E. If an importer loses the privilege in one IFO, he/she will lose it in all others. The IFO Supervisor should notify IID headquarters of action to rescind the approval.

VIII. SHIPPING PRIOR TO RECEIPT OF INCUBATION RESULTS

A. Permission to ship product before sample incubation is completed can be granted by the IFO Supervisor. A lot will be considered to have been inspected and passed and may be so stamped and released for shipment after all other assigned types of inspection have been sufficiently satisfied and the incubation samples taken, providing that conditions listed below under Sections B and C are met by the importer and the foreign establishment. Otherwise the entire lot will be held at the inspection site until the incubation and all other necessary inspection procedures have been satisfactorily completed.

B. Conditions for Prior Shipment After Samples Have Been Taken

1. **AIIS Inspection Levels.** The foreign establishment producing the product must have a good history of compliance for both the "Incubation" and "Condition of Container" examinations defined as being on Skip 1 or Skip 2 in the AIIS. If either one of these types of inspection are on "Normal" or "Tighten and Hold" when the assignment is drawn from the AIIS, the entire lot must be held until the incubation results are obtained and any other tests that may be indicated are satisfactorily completed.

2. **Letter Approval Date.** The importer must have a letter on file in the IFO covering the site at which the lot is being presented for inspection and provide a copy of the letter attached to the MP 410 marked with an approval notation from the IFO Supervisor to the inspector. The date of

the approval notation on the letter must be not more than one year earlier than the date of the MP 410. If this condition is not met, the entire lot must be held until the incubation results are obtained and any further tests are performed.

C. **Holding Released Product at a Warehouse.** If conditions listed in Section B have been met, the product controls assured by the importer must guarantee that product will not reach retail level distribution before incubation is completed and that product can be returned immediately to the inspection site should such action be requested by program officials. The lot must be held intact until the importer is notified by the inspector that incubation results are satisfactory. The importer must not sell the lot until incubation is completed.

IX. CHECKS ON LOCATION OF RELEASED PRODUCT

Periodically, but at least once a year, the IFO Supervisor will request that the importer disclose the location where a shipped lot will be on the date incubation is to be completed. The IFO Supervisor, with Compliance's assistance if necessary, will verify the locations of such released lots to ensure that they are not distributed to retail points before incubation results are obtained. A failure to readily locate the lot or a finding that the lot has moved beyond the stated location(s) will be considered cause to rescind the prior shipment approval.

X. NOTIFICATION

The importer will be notified of lot incubation results by the Import Field Office prior to release for retail sale. If a lot fails incubation, the importer will be notified by the Import Field Office to retrieve the product involved and present the reassembled lot at the import inspection location.

Patricia Stolfa

Deputy Administrator
International Programs

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,001.1 | 1-31-86

SAMPLES COLLECTED UNDER AUTHORITY OF SECTION 702 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

I. PURPOSE

This directive establishes policy and procedures to be followed by Science laboratories when handling, processing, storing, shipping and disposing of samples that may indicate a violation of the Federal Food, Drug and Cosmetic Act.

II. CANCELLATIONS

This directive supersedes all prior 702(b) policy memoranda.

III. (RESERVED)

IV. REFERENCES

Federal Food, Drug, and Cosmetic Act; §702(b); 21 USC 372.

V. DEFINITIONS

A. **702(b) Samples.** Samples requested by the Food and Drug Administration (FDA) under the authority of Section 702(b) of the Federal Food, Drug and Cosmetic Act. These samples include (1) domestic monitoring and surveillance samples with results exceeding established tolerance levels, and (2) microbiological domestic monitoring and surveillance samples with positive results which do not provide compound identity.

B. **Laboratory.** The three Field Service laboratories (FSL) in Athens, GA.; St. Louis, MO.; and Alameda, CA.

C. **702(b) Sample Log.** A computer listing providing a monthly report of 702(b) sample reserves forwarded to FDA (see format in Attachment 1).

DISTRIBUTION: Washington Offices; MPIO Regional Offices; Science Offices

OPI: SCI - Field Service Laboratories Division

VI. SCOPE

A. For the purpose of this directive, 702(b) samples refer to those whose analytical results indicate:

1. A residue in an edible tissue exceeding the FDA or EPA tolerance levels;

2. Extra-label drug use (if the finding is a violation of the Federal Food, Drug and Cosmetic Act);

3. Contamination by an industrial or environmental pollutant (with an established tolerance);

4. Samples whose results produce an Unidentified Microbial Inhibitor (UMI); or

5. A residue violation using in-plant tests for special programs (e.g., CAST).

B. 702(b) samples are limited to the following domestic residue sample types:

01 - Monitoring, National
02 - Monitoring, National, Excluding QA
03 - Monitoring, Area
04 - Monitoring, Domestic Plant Study
14 - Monitoring, National, First Time
15 - Monitoring, Area, First Time
21 - Surveillance, Domestic
22 - Surveillance - Domestic Follow-Up
23 - Surveillance, Inspector Generated
32 - Surveillance, In-Plant Positive
38 - Surveillance - Split

C. The following are **not** 702(b) samples:

1. Inedible tissues including injection sites (except for unapproved drug use);

2. Tissues that do not contain violative levels of residues (e.g., if a residue sample consists of liver, kidney, and muscle, and only the liver is in violation then the liver reserve is the only tissue forwarded under 702(b);

3. Samples containing residues which do not have an established tolerance.

VII. LABORATORY ACTION

A. **Initial Action**. If the sample result is above established tolerance, the reserve portion of the sample will be placed in a polyethylene bag (or other appropriate container) and sealed by the analyst. After

supervisory review and confirmation of the data entered on the official form, the reserve sample will be placed in frozen storage to maintain its integrity.

B. **No Reserve Tissue.** If all violative tissue is used-up during analysis, this should be noted on the official form. Send a copy of the official form to the appropriate FDA laboratory or District Office. Mark on the form that reserve tissue is unavailable. In the tissue column of the 702(b) Sample Reserve Status Report, enter N/A. If the sample represents a retained carcass or product, request guidance from the Director, FSLD, to determine if additional sampling for FDA is necessary. If additional tissue is necessary, the FSL will request the inspector to forward it directly to the appropriate FDA organization. The inspector will enter the form number of the analyzed sample in block 2 of FSIS Form 6000-1 and note "replacement tissue" and the original FSIS sample number in block 18.

C. **Storage and Shipping.** The laboratory will store all 702(b) sample reserves for a period of 1 month after the month of completion. On the first Monday of each month all eligible 702(b) reserves will be shipped to the FDA District office or laboratory having jurisdiction over the producer's business address. See Attachment 2 for FDA mailing addresses. Sample reserves should be batch-shipped using priority mail or other common courier. Each sample reserve should be clearly labeled and identified to allow matching of the reserve to its FSIS form. Before shipping, contact the appropriate FDA office and inform them of the shipment date and courier used. Follow appropriate procedures to assure sample integrity and condition during transit. A copy or facsimile of the FSIS Form must accompany each sample. For residues that deplete in storage, the analyst shall mark the form "Unstable Compound - Depletes in Storage."

Ronald E. Engel
Deputy Administrator
Science Program

Attachments

1 - 702(b) Sample Reserve Status Report
2 - FDA District Offices

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9205.1
REVISION 1

1/2/86

FRENCH LABELING REQUIREMENTS

I. PURPOSE

The purpose of this directive is to update labeling information required by France.

II. CANCELLATION

FSIS Directive 9205.1, dated 10/3/85.

III. [RESERVED]

IV. REFERENCES

Section 22.35, Meat and Poultry Inspection Manual.

V. REQUIREMENT

French inspection officials require new information on labels of meat and poultry products for export to France effective December 21, 1985.

This information updates existing label requirements described in Section 22.35 of the Meat and Poultry Inspection Manual. Other requirements of Section 22.35 remain in effect.

VI. LABELING REQUIREMENTS

In addition to USDA mandatory labeling information, all packaged food products must bear labels printed in French (bilingual is acceptable) and show the following information:

A. **Bulk And Consumer-Size Packages.**

1. Name of product including the physical state of the product, e.g., frozen pork livers.

2. Net quantity in metric units.

DISTRIBUTION: All MPI Offices. T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: IP/ECD

3. Full name and address of producer, packager, or EEC-recognized importer.

4. Country of origin.

5. List of ingredients, if applicable.

6. Lot identification, if applicable.

7. Slaughter or freezing date for fresh/frozen product; production date for processed product. See Paragraphs C.2. and C.5.

8. Optimal date of utilization or expiration date, as applicable. See Paragraphs C.3. and C.4.

9. Storage instructions including a recommended storage temperature, e.g., "Keep frozen. Store at ____°C or less."

B. **Consumer-Size Packages.** When applicable, the following information should be shown in addition to that of Paragraph A:

1. Directions for use.

2. Directions for special storage.

C. **Marking of Dates.**

1. General date format. Dates must be:

a. Uncoded.

b. In the following sequence: day, month, year.

c. Written with the month spelled out or abbreviated to three letters.

2. Date format/stability. Use the following format for food products with a stability of:

a. Less than 3 months: Day/Month.

b. Between 3 and 18 months: Month/Year.

c. More than 18 months: Year.

3. The optimal date of utilization. The following terms are specified in French for use with product which is stable:

a. Less than 3 months:

"A consommer de preference avant **(Day/Month)**." (To be consumed preferably before **(Day/Month)**.

b. Between 3 and 18 months:

"A consommer de preference avant fin **(Month/Year)**. (To be consumed preferably before the end of **(Month/Year)**.

c. More than 18 months:

"A consommer de preference avant fin **(Year)**." (To be consumed preferably before the end of **(Year)**.

4. The expiration date. The following products must bear an expiration date:

a. Those products perishable within a 6 week period.

b. Those products containing regulated materials for which an expiration date has been set. Fresh/frozen meats or poultry are not included in this group.

5. Production date. The production date may be the date of production or the date of packaging. The date may be indicated in one of the following ways:

a. Day/Month/Year.

b. A group of 4 or 5 numbers indicating the last number or the last 2 numbers of the year and 3 numbers from 001 to 366 indicating the day of production in the year.

c. Code dates may be used on certain retail products such as canned goods. Code information:

(1). Must be provided to the French Ministry of Agriculture prior to any sales of product in France.

(2). Should be directed to: la Direction de la Consommation et de la Repression des Fraudes, 13, rue Saint-Georges, 75436 PARIS CEDEX 09.

(3). Frozen products are not eligible to bear coded dates.

This information will be included in the comprehensive FSIS Directive for France to be issued at a later date.

Deputy Administrator
Meat and Poultry Inspection
Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9455.1 | 1/2/86

SPANISH LABELING REQUIREMENTS INCLUDING THE CANARY ISLANDS

I. PURPOSE

The purpose of this directive is to inform inspectors-in-charge and inspectors of requirements by Spanish officials.

II. CANCELLATIONS

FSIS Notice 72-84, dated 10/23/84.

III. RESERVED

IV. REFERENCE

MPI Manual 22.79

V. REQUIREMENT

Spanish inspection officials have informed FSIS that all packaged food products must bear labels printed in Spanish. Those labels must show the following information in addition to the requirements in section 22.79 of the MPI Manual.

A. Shipping Containers

1. Full name, address, and registration number of Spanish importer.

2. Weight in metric units.

3. Slaughter or freezing date for fresh/frozen product; production date for processed product.

4. Expiration or minimum duration date, as applicable, from paragraphs C and D of this directive.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, Science and Compliance Offices, T/A Plant Management, R&E, Import Offices, TRA, ABB

OPI: PP/RDU

B. Consumer Size Packages

1. Name of product.

2. List of ingredients.

3. Weight in metric units.

4. Directions for food preservation, if applicable.

5. Name and address of manufacturer, packer, or importer.

6. Identification of lot.

7. Country of origin.

8. Expiration or minimum duration date, as applicable, from paragraphs C and D of this notice.

C. Marking of Dates

1. The minimum duration date. For food products with a duration of:

a. Under 3 months, the following statement must be used: "To be consumed preferably prior to (day/month/year)".

b. Three to 18 months, use the following statement: "To be consumed preferably prior to (**month/year**)". This statement should be used for most fresh/frozen meat/poultry product.

c. More than 18 months, use the following statement: "To be consumed preferably before the end of (**year**)".

2. The expiration date. For food products which are microbiologically perishable within a short period of time, the expiration date must be shown as follows: "Expiration Date (**day/month/year**)".

D. Printing of Dates - All dates involved must be shown in the following manner:

1. The day, by the applicable digits(s).

2. The month, by its name or by the first three letters of the name.

3. The year, by its four digits or by its last two digits.

4. The order of dates used must be: day/month/year.

This information will be included in a comprehensive FSIS Directive on exports to Spain to be published at a later date.

Deputy Administrator
Meat and Poultry Inspection
Operations

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9620.1 | 1-23-86

INCUBATION REQUIREMENTS FOR SHELF-STABLE, HEAT-PROCESSED IMPORTED MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive contains the requirements for the incubation of shelf-stable, heat-processed imported meat and poultry products and provides procedures and requirements for shipping these products before incubation results are obtained.

II. CANCELLATION
(RESERVED)

III. (RESERVED)

IV. REFERENCES

A. Sections 318.11(i) and 327.6 of the Federal meat inspection regulations, and sections 381.149(g) and 381.199(a)(1)-(4) of the poultry products inspection regulations.

B. Sections 18.47, 27.12, and 27.16 of the Meat and Poultry Inspection Manual.

V. DEFINITIONS AND FORMS

The following terms used in this directive are defined as follows:

Importer: The person, company or brokerage firm applying for inspection of imported meat and poultry products, as identified in Section A.1. of the MP Form 410.

MP Form 410: Import Inspection Application and Report.

Warehouse: A storage location where retail trade in meat and poultry products is not conducted.

Retail: Trade directly to consumers.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: Import Inspection Division, IP

VI. GENERAL REQUIREMENTS

A. **Products to be Incubated.** Incubation requirements as set forth in section 327.6 of the regulations apply to all thermally processed product packed in hermetically sealed containers that are intended to be shelf-stable under normal nonrefrigerated conditions.

B. **Purpose of Incubation**

The purpose of incubation is to provide increased assurance of the safety and stability of shelf-stable canned product.

C. **Sampling.** The Automated Import Information System (AIIS) may assign incubation to any lot of imported shelf-stable canned product based on a history of producing plant performance. Inspectors may choose to sample lots not assigned incubation by the AIIS when they have reason to suspect any problems. The random numbers for sampling the lot shall be drawn from the AIIS after any presorting of transportation-damaged cans or immediate containers by the importer. Using those random numbers, the inspector shall select 24 sample units from the lot for incubation.

D. **Temperature, Time and Equipment Requirements**

1. Incubation of sample units shall be in accordance with sections 318.11(i)(4), 327.6(1), and 381.149(g)(1) of the regulations; and sections 18.47(b)(1) and 27.16(c) and (e) of the Meat and Poultry Inspection Manual.

2. The inspector will check the temperature and samples daily, if possible, but at least twice during the 10-day cycle.

E. **Facilities**

The necessary incubation facilities shall be provided by the importer as required by section 327.6(e) of the regulations.

F. **Security.** When in use, the inspector shall keep the incubator and incubating samples under lock or under his or her personal supervision at all times.

G. **Records.** The inspector shall keep records which include the number of the MP 410, lot numbers of all samples in the incubator, code identification of all samples, the date the samples were placed in the incubator, the date the cans or immediate containers are to be taken out, the dates on which the temperature was checked, and the current lot status.

VII. APPLICATION FOR PRIOR SHIPMENT APPROVAL

A. Permission to move the product before the incubation results are received is a privilege granted to an importer, not to producing establishments. The importer must request and be granted permission in writing by the Import Field Office (IFO) Supervisor at each Import Field Office he/she deals with.

B. The letter of application must include the following details:

1. How and to which warehouses product might be transported and how control of the product will be maintained.

2. Guarantees that the product will not be distributed to retail points and will be kept intact so that it may be retrieved if a recall is necessary.

3. A description of the retrieval procedures.

C. Permission to ship product before incubation ends may be granted on a case-by-case basis to importers.

D. The written permission of the IFO Supervisor will take the form of a handwritten notation "Approved" on the letter of application and must show the IFO Supervisor's signature and a date. A copy of the letter with the approval notation will be kept on file in the IFO. Permission must be renewed annually.

E. If an importer loses the privilege in one IFO, he/she will lose it in all others. The IFO Supervisor should notify IID headquarters of action to rescind the approval.

VIII. SHIPPING PRIOR TO RECEIPT OF INCUBATION RESULTS

A. Permission to ship product before sample incubation is completed can be granted by the IFO Supervisor. A lot will be considered to have been inspected and passed and may be so stamped and released for shipment after all other assigned types of inspection have been sufficiently satisfied and the incubation samples taken, providing that conditions listed below under Sections B and C are met by the importer and the foreign establishment. Otherwise the entire lot will be held at the inspection site until the incubation and all other necessary inspection procedures have been satisfactorily completed.

B. Conditions for Prior Shipment After Samples Have Been Taken

1. **AIIS Inspection Levels.** The foreign establishment producing the product must have a good history of compliance for both the "Incubation" and "Condition of Container" examinations defined as being on Skip 1 or Skip 2 in the AIIS. If either one of these types of inspection are on "Normal" or "Tighten and Hold" when the assignment is drawn from the AIIS, the entire lot must be held until the incubation results are obtained and any other tests that may be indicated are satisfactorily completed.

2. **Letter Approval Date.** The importer must have a letter on file in the IFO covering the site at which the lot is being presented for inspection and provide a copy of the letter attached to the MP 410 marked with an approval notation from the IFO Supervisor to the inspector. The date of

the approval notation on the letter must be not more than one year earlier than the date of the MP 410. If this condition is not met, the entire lot must be held until the incubation results are obtained and any further tests are performed.

C. **Holding Released Product at a Warehouse.** If conditions listed in Section B have been met, the product controls assured by the importer must guarantee that product will not reach retail level distribution before incubation is completed and that product can be returned immediately to the inspection site should such action be requested by program officials. The lot must be held intact until the importer is notified by the inspector that incubation results are satisfactory. The importer must not sell the lot until incubation is completed.

IX. CHECKS ON LOCATION OF RELEASED PRODUCT

Periodically, but at least once a year, the IFO Supervisor will request that the importer disclose the location where a shipped lot will be on the date incubation is to be completed. The IFO Supervisor, with Compliance's assistance if necessary, will verify the locations of such released lots to ensure that they are not distributed to retail points before incubation results are obtained. A failure to readily locate the lot or a finding that the lot has moved beyond the stated location(s) will be considered cause to rescind the prior shipment approval.

X. NOTIFICATION

The importer will be notified of lot incubation results by the Import Field Office prior to release for retail sale. If a lot fails incubation, the importer will be notified by the Import Field Office to retrieve the product involved and present the reassembled lot at the import inspection location.

Patricia Stolfa

Deputy Administrator
International Programs

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,001.1 | 1-31-86

SAMPLES COLLECTED UNDER AUTHORITY OF SECTION 702 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

I. PURPOSE

This directive establishes policy and procedures to be followed by Science laboratories when handling, processing, storing, shipping and disposing of samples that may indicate a violation of the Federal Food, Drug and Cosmetic Act.

II. CANCELLATIONS

This directive supersedes all prior 702(b) policy memoranda.

III. (RESERVED)

IV. REFERENCES

Federal Food, Drug, and Cosmetic Act; §702(b); 21 USC 372.

V. DEFINITIONS

A. **702(b) Samples.** Samples requested by the Food and Drug Administration (FDA) under the authority of Section 702(b) of the Federal Food, Drug and Cosmetic Act. These samples include (1) domestic monitoring and surveillance samples with results exceeding established tolerance levels, and (2) microbiological domestic monitoring and surveillance samples with positive results which do not provide compound identity.

B. **Laboratory.** The three Field Service laboratories (FSL) in Athens, GA.; St. Louis, MO.; and Alameda, CA.

C. **702(b) Sample Log.** A computer listing providing a monthly report of 702(b) sample reserves forwarded to FDA (see format in Attachment 1).

DISTRIBUTION: Washington Offices; MPIO Regional Offices; Science Offices

OPI: SCI - Field Service Laboratories Division

VI. SCOPE

A. For the purpose of this directive, 702(b) samples refer to those whose analytical results indicate:

1. A residue in an edible tissue exceeding the FDA or EPA tolerance levels;

2. Extra-label drug use (if the finding is a violation of the Federal Food, Drug and Cosmetic Act);

3. Contamination by an industrial or environmental pollutant (with an established tolerance);

4. Samples whose results produce an Unidentified Microbial Inhibitor (UMI); or

5. A residue violation using in-plant tests for special programs (e.g., CAST).

B. 702(b) samples are limited to the following domestic residue sample types:

01 - Monitoring, National
02 - Monitoring, National, Excluding QA
03 - Monitoring, Area
04 - Monitoring, Domestic Plant Study
14 - Monitoring, National, First Time
15 - Monitoring, Area, First Time
21 - Surveillance, Domestic
22 - Surveillance - Domestic Follow-Up
23 - Surveillance, Inspector Generated
32 - Surveillance, In-Plant Positive
38 - Surveillance - Split

C. The following are **not** 702(b) samples:

1. Inedible tissues including injection sites (except for unapproved drug use);

2. Tissues that do not contain violative levels of residues (e.g., if a residue sample consists of liver, kidney, and muscle, and only the liver is in violation then the liver reserve is the only tissue forwarded under 702(b);

3. Samples containing residues which do not have an established tolerance.

VII. LABORATORY ACTION

A. **Initial Action.** If the sample result is above established tolerance, the reserve portion of the sample will be placed in a polyethylene bag (or other appropriate container) and sealed by the analyst. After

supervisory review and confirmation of the data entered on the official form, the reserve sample will be placed in frozen storage to maintain its integrity.

B. **No Reserve Tissue.** If all violative tissue is used-up during analysis, this should be noted on the official form. Send a copy of the official form to the appropriate FDA laboratory or District Office. Mark on the form that reserve tissue is unavailable. In the tissue column of the 702(b) Sample Reserve Status Report, enter N/A. If the sample represents a retained carcass or product, request guidance from the Director, FSLD, to determine if additional sampling for FDA is necessary. If additional tissue is necessary, the FSL will request the inspector to forward it directly to the appropriate FDA organization. The inspector will enter the form number of the analyzed sample in block 2 of FSIS Form 6000-1 and note "replacement tissue" and the original FSIS sample number in block 18.

C. **Storage and Shipping.** The laboratory will store all 702(b) sample reserves for a period of 1 month after the month of completion. On the first Monday of each month all eligible 702(b) reserves will be shipped to the FDA District office or laboratory having jurisdiction over the producer's business address. See Attachment 2 for FDA mailing addresses. Sample reserves should be batch-shipped using priority mail or other common courier. Each sample reserve should be clearly labeled and identified to allow matching of the reserve to its FSIS form. Before shipping, contact the appropriate FDA office and inform them of the shipment date and courier used. Follow appropriate procedures to assure sample integrity and condition during transit. A copy or facsimile of the FSIS Form must accompany each sample. For residues that deplete in storage, the analyst shall mark the form "Unstable Compound - Depletes in Storage."

Ronald E. Engel
Deputy Administrator
Science Program

Attachments

1 - 702(b) Sample Reserve Status Report
2 - FDA District Offices

Attachment 1

702(b) SAMPLE RESERVE STATUS REPORT

LABORATORY NO.

FORM NO.	DATE REC	DATE ANALYZED	EST NO.	PRODUCER NAME & ADDRESS	RES TEST	TISSUE	RESULT	FORWARDED TO FDA LAB NO.	DATE FORWARDED

FDA DISTRICT OFFICES

Program Monitor	FDA District	Lab No.	Lab Address	States Serviced
Eugene Marong 223-3175	Boston	2511	FDA Attn: Sample Custodian 585 Commercial St. Boston, MA 02109	Connecticut Maine Massachusetts New Hampshire Rhode Island Vermont
David Kiesling 437-4462	Buffalo	3611	FDA Attn: Sample Custodian 599 Delaware Ave. Buffalo, NY 14202	New York
Robert Dieninger 488-5389 Kathy Miraccor 663-5060	Newark Brooklyn	3612	FDA-New York Regional Laboratory Attn: Sample Custodian 7th Floor 830 3rd Avenue Brooklyn, NY 11232-1593	New Jersey New York (city only)
George Gonzalez (809) 753-4495	San Juan	4311	FDA Attn: Sample Custodian U.S. Post Office & Courthouse (Office G1) Ricinto Sur Street Old San Juan, PR 00905	Puerto Rico
Lloyd McEwen 925-2564	Baltimore	2411	FDA Attn: Sample Custodian 900 Madison Ave. Baltimore, MD 21201	Maryland Virginia West Virginia
Ray Arzylowitcz 597-0492	Philadelphi	4211	FDA Attn: Sample Custodian Room 900, U.S. Customhouse 2nd & Chestnut Streets Philadelphia, PA 19106	Delaware Pennsylvania

FDA DISTRICT OFFICES
(continued)

Program Monitor	FDA District	Lab No.	Lab Address	States Serviced
William Miller 257-2186 Anthony Able 852-5171 Lloyd Bush 820-6281	Atlanta Nashville Orlando	1311	FDA-Atlanta Regional Laboratory Attn: Sample Custodian 60 8th Street, NE Atlanta, GA 30309	Alabama Florida Georgia Kentucky Mississippi North & South Carolina Tennessee
Lynn Swann 955-4792	Chicago	1711	FDA IITRI Attn: Sample Custodian 3441 South Federal Street Chicago, Il 60616	Illinois
Terry Bolen 684-0506	Cincinnati	3911	FDA Attn: Sample Custodian 1141 Central Parkway Cincinnati, OH 45202	Ohio
Eugene Spiuack 226-6260	Detroit	2611	FDA Attn: Sample Custodian 1560 E. Jefferson Detroit, MI 48207	Indiana Michigan
James Egenberger 787-3923	Minneapolis	2711	FDA Attn: Sample Custodian 240 Hennepin Ave. Minneapolis, MN 55401	Minnesota Wisconsin
Gary Pierce 729-0312	Dal as Houston	4811	FDA Attn: Sample Custodian 3032 Bryan Street Dallas, TX 75204-6191	New Mexico Oklahoma Texas

FDA DISTRICT OFFICES
(continued

Program Monitor	FDA District	Lab No.	Lab Address	States Serviced
Michelle Berry 758-5623	New Orleans	2211	FDA Attn: Sample Custodian 4298 Elysian Fields Avenue New Orleans, LA 70122	Arkansas Louisiana
Richard Turner 279-4137	Kansas City St. Louis	2911	FDA Attn: Sample Custodian 1009 Cherry St. Kansas City, MO 64106	Iowa Kansas Missouri Nebraska
Edward Sterner 564-4915	Denver	0811	FDA Attn: Sample Custodian Room 500 New Custom House Denver, CO 80202	Colorado Montana North & South Dakota Utah Wyoming
Marvin Appleton 798-3356	Los Angeles	0611	FDA Attn: Sample Custodian 1521 West Pico Boulevard Los Angeles, CA 90015	California [1/] Arizona
Dale Kennen 556-6163	San Francisco	0612	FDA Attn: Sample Custodian Room 526, U.N. Plaza San Francisco, CA 94102	California [1/] Hawaii Nevada
James Davis 399-5319	Seattle	5311	FDA Attn: Sample Custodian 5009 Federal Office Bldg. 909 First Ave. Seattle, WA 98174	Alaska Idaho Oregon

1/ California samples from the following counties go to Los Angeles: Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara, and Ventura. All others go to San Francisco. If county is unknown, call FDA for assistance.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,012.1 | 11-20-85

UNIDENTIFIABLE MICROBIAL INHIBITION

I. PURPOSE

This Directive describes FSIS policy and identifies organizational responsibilities to detect, report, and track unidentifiable microbial inhibition resulting from microbioassay of meat and poultry tissues for incurred antibiotic residues.

II. (RESERVED)

III. REASON FOR ISSUANCE

To provide guidance in recognizing and managing UMIs.

IV. (RESERVED)

V. FORMS AND/ABBREVIATIONS

The following will appear in their abbreviated form in this Directive:

MIC	Microbiologist in Charge
MD	Microbiology Division
FSLD	Field Service Laboratories Division
FSL	Field Service Laboratory
REPD	Residue Evaluation and Planning Division
SCI	Science Program
UMI	Unidentifiable Microbial Inhibition
210	Reporting Code for UMI
FSQS Form 6000-1	Laboratory Report
FSIS Form 6000-2	Monitoring Residue Program
FSQS Form 6000-4	Import Residue Program

VI. POLICY

FSIS will report UMIs when they are found in the official bioassays. UMI data will be periodically reviewed for frequency of occurrence, species, geographic source, etc., in order to correlate drug usage changes for possible

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: SC/MD

identification. Implementation of new compound identification tests after satisfactory evaluation by MD will be done, as soon as possible, at the FSL's to reduce the incidence of UMIs.

VII. DEFINITION

Unidentifiable Microbial Inhibition: The end result and report of antimicrobial activity in tissue that cannot be specifically identified as to compound by on-line technology at SCI laboratories.

VIII. PROCEDURES/RESPONSIBILITIES

This section describes the procedure for assuring that an UMI is unidentifiable by on-line technology at FSL's laboratories and identifies responsibilities for accomplishing the procedure, reporting the criteria, and tracking the procedures.

A. RECOGNIZING UMIs. The responsible microbiologist/technician will follow established analytical procedures supplemented by the most current instructions issued by the Director, MD, with the concurrence of the Director, FSLD, in analyzing tissue samples for antibiotic residues. Upon exhausting all available microbiological testing relative to identifying specific antibiotics, the microbiologist or technician will report an UMI on the appropriate laboratory report form. The MIC will concur that the UMI report is valid and will send the sample and sample form to the chemistry laboratory for possible further testing. If additional chemical testing is not warranted, the MIC will report the UMI finding. Results of chemical analysis from UMI samples will be reported in accordance with the chemistry reporting procedures.

If there is an insufficient sample to complete all the tests necessary for identifying the antimicrobial response, the results will not be reported as an UMI. Instead, the microbiologist or technician will report those compounds definitely found and for those not completed will write on the form "Insufficient sample available to complete identification of antimicrobial response."

To report a case as an UMI, each tissue demonstrating an analytical response must be carried through the complete analytical process before reporting an UMI finding.

B. REPORTING UMIs. The UMI result will be indicated on FSIS Forms 6000-1 or 6000-2 by the Code "210", followed by the appropriate tissue code, followed by the quantitation code "----", indicating the UMI is not quantifiable. An example for reporting an UMI detected in a kidney sample is: 210-4 "----".

C. DATA ENTRY. Data generated from UMI samples will be entered into the Laboratory Sample Flow System by each laboratory using standard operating procedures. The report quantitation code "----" will be entered as "9999".

D. DATA EVALUATION. On a weekly basis, the MIC at each laboratory will send copies of all UMI case reports along with the corresponding in-house bioassay result forms to the Director, MD, for staff review and evaluation. These copies of UMI cases are those reported out for the prior week. The MD will monitor the reports to evaluate the data and make recommendations for further analytical work or test interpretations. The REPD will conduct epidemiological evaluations of UMI findings to identify unusual field therapy. The MD will be furnished this information to evaluate the need for method modifications.

Ronald E Engel

Deputy Administrator
Science Program

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

☒ DIRECTIVE
☐ REVISION
☐ AMENDMENT
☒ OTHER

USE OF DISPOSABLE SHIPPING CONTAINERS	10140.1	11-5-85

I. PURPOSE

This document transmits FSIS Directive 10140.1, Use of Disposable Shipping Containers, and provides procedures for control and disposition of "Film-Box Containers."

II. BACKGROUND

To improve utilization of Food Safety and Inspection Service resources, it has been decided to replace the film-box with the disposable shipping container (DSC) for mailing food chemistry samples. Field testing has demonstrated that samples shipped using the DSC arrive at a Field Service or Contract Laboratory in an acceptable condition at a rate at least equal to samples shipped using the film-box. Postage savings (i.e., the cost of mailing back the empty film-box to plant inspectors), the new box's durability, and reduced storage space support the use of the disposable shipping container as an effective and efficient replacement for the film-box.

III. PROCEDURES--FILM-BOX CONTAINERS

Initial shipment of DSC materials will include "Red Dot" adhesive markers. These markers will be used by the Field Service and Contract Laboratories to determine that inspectors have received their initial supply of DSCs and that the marked film-box container should not be returned to the inspector.

A. FSIS inspector shall affix "Red Dot" markers to all film-box containers prior to shipping samples only to the Field Service Laboratory or Contract Laboratory.

B. FSIS Laboratories.

1. Field Service Laboratories.

a. Field Service Laboratories will discard any film boxes that exhibit tears, crushed corners, soil, frayed or broken straps or unservisable address holders.

b. Retain all "Red Dot" film boxes until further instruction from Director, FSLD.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, TRA, ABB, R&E, AM Offices

OPI: Science Program

c. Return all unmarked film boxes to the establishment until further notice.

2. Contract Laboratories. Transship all "Red Dot" film boxes to the appropriate Field Service Laboratory and continue to return all unmarked film boxes to the establishments until further notice.

C. Accredited Laboratories and Official Establishments. This directive will not change shipping procedures between the Accredited Laboratory and the Official Establishment.

Acting Administrator

Attachment

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10140.1 | 11-5-85

USE OF DISPOSABLE SHIPPING CONTAINERS

I. PURPOSE

This directive prescribes the use and procedures for obtaining supplies of disposable shipping containers. The one-way disposable shipping container is intended primarily for use by plant inspectors to mail food chemistry samples which do not require insulation or other special handling.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

Section 23.5, Meat and Poultry Inspection Manual; most current FSIS Notice on "Change of Destination Laboratories for Certain Samples."

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated or otherwise referred to in this directive.

ASD	Administrative Services Division
DSC	Disposable Shipping Container
PSB	Program Services Branch, ASD
MPIO	Meat and Poultry Inspection Operations
RO	Regional Office

MP Forms 128 through 128-6, color-coded, preaddressed, pressure sensitive mailing labels:

MP Form 128	Eastern Laboratory	(green)
MP Form 128-1	Webb Foodlab, Inc	(blue)
MP Form 128-2	Midwestern Laboratory	(red)
MP Form 128-3	Kentucky State Laboratory	(salmon)
MP Form 128-4	Western Laboratory	(orange)

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, TRA, ABB, R&E, AM Offices

OPI: Science Program

MP Form 128-5	California State Laboratory	(brown)
MP Form 128-6	(not preaddressed) 1/	(black)

1/ This form is reserved for DSC use to mail samples to locations other than listed above.

VI. POLICY

A. DSCs will be used to ship food chemistry samples (i.e., added water, added substance or total fat analysis) to the Field Service Laboratories and Contract Laboratories to the fullest extent possible. DO NOT USE DSCs if:

1. Use of the DSC is not practical, or

2. Instructions for mailing a particular sample or type of sample state otherwise.

B. The following are considered DSC materials:

1. Box, shipping, corrugated (6 3/4" X 6 3/4" X 7½", 275 lbs. bursting strength).

2. Tape, polypropelyene (2" width).

3. Bag, plastic sample (see section 23.5 of the Meat and Poultry Inspection Manual for specifications).

4. Rubber bands.

5. Label, mailing, preaddressed, pressure sensitive, color-coded, preprinted with PRIORITY MAIL, PERISHABLE.

VII. RESPONSIBILITIES

A. MPIO

The MPIO, RO, shall provide a projected estimate for the number of food chemistry samples, by region, to PSB. This will enable PSB and the regions to determine each region's DSC material requirements.

B. Program Services Branch, ASD

1. Initial Supply

a. Determine the amount of DSC materials to be ordered using the information provided in the latest FSIS Notice on "Change of Destination Laboratories for Certain Samples."

b. Order and receive the **INITIAL** consolidated consignment of DSC materials.

c. Distribute the **INITIAL** supply of DSC materials to the headquarter plants or non-patrol establishments.

2. Resupply

a. Determine the amounts of DSC materials to be ordered, based on requests from the regions.

b. Place consolidated orders for bulk shipments to REPLENISH regional DSC inventories.

c. Inform the regions of expected delivery dates.

d. Determine and maintain an adequate backup supply of DSC materials for the regions, the Agency's other users and special projects.

C. **Regional Offices**

1. Determine adequate supply levels based on stock levels and MPIO estimates for food chemistry samples.

2. Contact PSB for DSC supplies.

3. Distribute DSC materials to REPLENISH stock levels at headquarter plants or non-patrol establishments (the initial distribution will be handled by PSB).

4. Maintain an adequate backup supply of DSC materials for the plant inspectors. It is recommended to establish the DSC stock at a 1-month level.

D. **FSIS Inspectors**

1. Disposable Shipping Container

a. Use DSC to ship food chemistry samples (i.e., added water, added substance or total fat analysis) to the Field Service Laboratories or Contract Laboratories to the fullest extent possible.

b. Maintain an adequate stock of DSC materials.

(1) Subsequent to receiving initial stock of DSC materials, it is recommended that inspectors maintain the stock at a 6 to 12-month level. When reordering, it may be necessary to increase or decrease the number from the initial supply as appropriate to maintain an adequate supply. Do not allow stock to fall below a 2-month supply level before reordering.

(2). To replenish DSC materials, contact Regional Office through normal channels. Allow 3 weeks for DSC material deliveries.

2. Film-Box Container. Upon receipt of DSC materials, use film boxes on hand only for shipment of food chemistry samples to the Field Service or Contract Laboratory until film-box stock is depleted.

E. **Field Service Laboratories and Contract Laboratories**

1. Disposable Shipping Container

a. Handle sample received by DSC as prescribed in section 23.5 of the Meat and Poultry Inspection Manual.

b. Dispose of the used DSC as prescribed by Science policy and/or PSB.

2. Film Box Containers. Handle sample received by film box container as prescribed in section 23.5 of the Meat and Poultry Inspection Manual.

F. L. Gast

Acting Administrator

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,625.1 | 2-26-86

PROCEDURES FOR EVIDENTIARY SAMPLES

I. PURPOSE

This Directive establishes policy and procedures to be followed by Science Laboratories when receiving, handling, processing and disposing of samples which may be used as evidence in a court of law. These samples may include, but are not limited to, those originating from the Compliance Program Epidemiology activities, Emergency Programs, Contamination Response System, consumer complaints, Office of the Inspector General, Food and Drug Administration, and other special samples submitted by field personnel. These samples are referred to herein as Evidentiary Samples.

II. [RESERVED]

III. REASON FOR ISSUANCE

Agency personnel may be required to testify regarding samples offered as evidence in Federal court proceedings. If FSIS is requested to provide a sample and associated laboratory documentation as evidence for a trial, an Agency employee may be required to testify that the evidence is authentic. Therefore, samples that are to be introduced as evidence must have been controlled in a manner that allows FSIS to demonstrate that: (1) the sample has been identified correctly; (2) that custody has been adequately controlled and thoroughly documented during the period the sample was in laboratory possession; and (3) the sample itself has not been altered in any way by parties other than the sample preparer and the analyst (Note: The preparer and analyst may alter the sample in ways such as grinding and removing a small portion of the sample for analysis). This control ensures "sample integrity", that is, the sample has not been lost, tampered with or otherwise rendered inadmissable as evidence in a future legal proceeding.

DISTRIBUTION: All MPI Offices, Science and Compliance Washington Offices, T/A Inspectors, Plant Management

OPI: Science Program/FSLD

Sample integrity is achieved by:

A. Thorough documentation of:

1. Sample transfer from collecting person to laboratory receipt;

2. Condition of sample upon receipt by the laboratory;

3. Procedures performed upon the sample while under laboratory control;

4. All persons who had access to the sample, including times of access and reasons for access.

B. Security of the sample, i.e., restricting access to it.

C. Demonstration that the sample was secured at all times and never left unattended while under laboratory control.

IV. POLICY

It is the policy of FSIS laboratories to control evidentiary samples in accordance with the Federal Rules of Evidence and judicial standards. This is to assure that:

A. Sample integrity and identity are maintained;

B. Analytical findings are reliable, accurate, and supportable; and

C. The chain of custody of the sample will withstand cross-examination in the event that the sample and/or laboratory results are introduced into evidence at a trial.

V. REFERENCES

FSIS Directives 8150.1, 8410.1, 10600.1 and 10600.2; Meat and Poultry Inspection Manual, Part 23A; MPI Bulletin 83-26.

VI. DEFINITIONS:

A. **Laboratory** - includes the three Field Service Laboratories (Athens, Ga.; St. Louis, Mo.; and Alameda, Ca.) and the Beltsville National Laboratories, Beltsville, Md.

B. **Laboratory Director** - includes the Directors of the three Field Service Laboratories and the Branch Chiefs of the Beltsville National Laboratories.

C. **Responsible Supervisor** - includes In-Charges and First Line Supervisors (for Chemistry, Pathology, and Microbiology) in the Field Service Laboratories, and the Section Chiefs in the Beltsville National Laboratories.

D. **Responsible Analyst** - is the lead analyst to whom the sample is assigned.

E. **Sample Custodian**-person at laboratory responsible for control of evidentiary sample.

VII. INITIAL CONTROL

A. Designating a Sample Custodian

1. Each laboratory shall assign one person and a back-up as Sample Custodian for sample receipt and control. In addition, this person will supervise mailroom activities.

B. Identification

1. Most evidentiary samples originate from Compliance Division investigations. All Compliance Division investigatory samples shall be sealed with FSIS Form 8040-1, "OFFICIAL SEAL" (See FSIS Directive 8150.1: "Sample Collection and Integrity"). Samples originating from consumer complaints, amenability, epidemiology and emergency programs shall not be sealed unless instructed by the area office. However, a "Priority Sample Sticker," FSIS Form 8000-12, shall be placed on the outside shipping container of all samples submitted by the Compliance Program.

2. Evidentiary samples are identified by the seal on the closure of the **internal** container (e.g., the neck or flap of the bag containing the sample). If possible, all products (including intact cans or jars) should be individually placed in separate polyethylene bags. For jars that cannot be placed in a polyethylene bag, a seal should be placed at the juncture of the lid and glass container. For other container types, the seal should be attached so that tampering would damage the seal. Seals should tear or self destruct upon removal or tampering.

3. Unsealed samples subsequently identified as evidentiary samples are to be immediately secured. The Sample Custodian must notify the Laboratory Director, who will contact the Director, FSLD, for instructions on how to proceed.

NOTE: The Compliance Division is the only FSIS program authorized to use the "Official Seal" (FSIS Form 8040-1). If other programs initiate special seals for the same purpose, the procedures in this directive shall apply.

C. Processing.

1. After receipt and identification, the evidentiary sample shall be taken to the Sample Custodian. If a sample is received beyond the normal tour of duty, the carton shall be secured in locked storage until the next working day.

2. If the sample is received during the normal tour of duty but analysis cannot be initiated immediately, the Sample Custodian shall secure the sample in appropriate storage.

3. If, upon receipt, the seal is intact, the Sample Custodian shall:

a. Examine the enclosed form(s) to determine the analytical unit; and

b. Initiate an Evidentiary Sample Control Form (Attachment 1) and complete blocks 1 through 13. If the sample has been shipped by other than normal mail, shipping documentation will be kept with the official form.

4. If, upon receipt, the seal(s) is not intact or tampering is obvious, the Sample Custodian shall alert the Laboratory Director, who will then notify the organization that submitted the sample. The sample will be secured, as specified in Section IX, pending instructions to proceed.

D. **Routing.**

1. After completing the required documentation, the Sample Custodian shall personally submit the sample to the Responsible Supervisor (RS), who signs and dates the Evidentiary Sample Control Form.

2. If the sample requires microbiological analysis, the Sample Custodian shall deliver the sample to the RS in microbiology. If the RS for microbiology suspects a public health hazard, he/she must immediately notify the Meatborne Hazard Control Center and other appropriate personnel if warranted.

VIII. SUPERVISORY CONTROL

A. **Sample Receipt.**

The Responsible Supervisor shall accept the Evidentiary Sample and associated documents from the Sample Custodian and sign and date the control form. The Sample Custodian retains the carbon copy of the control form for the laboratory file on that evidentiary sample. The RS will then assign the sample to an analyst.

B. **Analysis**

The Analyst:

1. Accepts the sample and signs and dates the control form. The Evidentiary Sample Control Form and associated control documents (e.g., Registered or Certified Mail receipts and seals) must accompany the sample until the analysis is completed. After initial entry into the Laboratory Sample Flow System (LSFS), the official form is returned to the responsible analyst to accompany the sample through processing.

2. Breaks the seal (if the seal is intact). He/she then initials and dates the broken seal but does not remove it. He/she examines the sample to determine if it is in condition suitable for analysis.

3. Removes only the required quantity of sample necessary to perform the analysis and retains the sample in the internal container with its broken seal.

4. Places the unused sample portion in a bag together with the original bag or container and seals it with a sealing bar. It is then placed in a second bag and sealed with a sealing bar. Prior to sealing, the analyst will write the form number and sign and date the area where the sealing bar will be applied. If the sample is contained in something other than a bag (e.g., canned product), follow the same procedures outlined above, except retain the sample's commercial label and container identification (e.g., a can lid with the serial number). This information shall be placed in a third bag and sealed as above. The reserve is returned for secure storage to the Sample Custodian who signs and dates the control form.

5. Supervises sample preparation personnally if sample preparation is required by someone other than the responsible analyst.

6. Completes the analysis. The analyst then discusses the analytical findings, interpretation, and recording of results with his/her supervisor. If the analysis requires more than one working day, the sample shall be returned to the Sample Custodian for secured storage. This transaction must be documented.

C. Final Processing

Upon completion of the sample and related documentation, the analyst will:

1. Convey the remaining portion of the sample to the Sample Custodian for control and secure storage.

2. Review and complete data entry on the laboratory form(s) and forward to LSFS for results entry.

3. Prepare a contents list for each sample file. The list is verified by the Sample Custodian.

4. Forward all documentation to the RS. The documentation should include the original Evidentiary Sample Control Form, supporting reports, official forms(s), other documentation, and the internal seal(s).

IX. STORAGE

A. Samples

1. The RS will ensure that sensitive samples are stored in a secured area. Access should be limited to the Sample Custodian and back-up.

2. The Sample Custodian will maintain sample security.

3. Persons receiving the sample from the Sample Custodian will sign out and in for the sample on the control form.

B. Sample Files

Keep in secure storage. Access to the sample file shall be authorized only by the RS.

X. RETESTING AND TRANSFERRING

A. Retesting in Receiving Laboratory

All control procedures provided for initial analysis, final processing and storage in Sections VIII B, VIII C, and IX must be followed if a decision to retest is made subsequent to conveyance of sample custody after completion by the initial analyst.

B. Transfer to Other Government Laboratory

The surrendering laboratory will:

1. Create a record of the transfer for its files, including photo-copies of all transferred documents.

2. Transship the sample and all original documents to the new location. The receiving organization shall return to the originating laboratory a signed receipt which is placed in the file containing copies of the transferred records.

XI. REMOVAL

A. Authorization

Division directors must provide written authorization to the Laboratory Director for removal of a sample.

B. Transshipping

The person receiving the sample (including employees of the U.S. Postal Service and other common carriers) must present proper identification and sign for the sample prior to release. The Sample Custodian will control this process.

C. Opposing Litigant Party

1. A sample or associated documentation shall not be surrendered to the opposing party without a court order, which will be relayed through channels to the Laboratory Director. If issued, the terms of the court order will be followed. If the litigant is allowed access to the sample or documentation at the laboratory by terms of a court order, an appropriate staff member will accompany him/her during direct access.

2. A sample or documentation also may be surrendered upon written request from the Office of General Counsel.

XII. DISPOSAL OF EVIDENTIARY SAMPLES

A. Authorization

Disposal of evidentiary samples requires written direction from a Division Director, who shall issue disposal orders upon written authorization by a responsible official of the originating organization. The Compliance Program lists of their samples to be discarded also constitute disposal authorization.

B. Disposal Conditions

1. Generally, samples are not destroyed until litigation is completed (including appeals in case of re-trial).

2. The Laboratory Director will enter the written authorization in the sample file and give the file to the Sample Custodian, along with sample disposal instructions.

3. The Sample Custodian will update the last line of the Evidentiary Sample Control Form upon disposal. The form will then be placed in the sample file. The sample file will be retained in accordance with FSIS records retention schedules.

Ronald E Engel
Deputy Administrator
Science Program

ATTACHMENT
FSIS Form 10625-1 (10/85) Evidentiary Sample Control Form

Attachment

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **EVIDENTIARY SAMPLE CONTROL FORM**	1. LABORATORY CODE	2. ESTABLISHMENT NO.	3. OFFICIAL FORM NO.
	4. INTERNAL LAB NO.	5. CASE NO.	6. OTHER ID NUMBER
7. ORIGINATING ORGANIZATION	8. NAME AND ADDRESS OF PRODUCER OR CONSUMER		
9. PRODUCT NAME/OR SPECIES AND TISSUE(S)	10. DATE SHIPPED	11. SHIPPED BY	12. SHIPPER'S CONTROL NO.
13. RECEIVED BY *(Signature)*	DATE	14. CONDITION	

15. CHAIN OF CUSTODY

	DATE & TIME	FROM *(Sign Name)*	TO *(Sign Name)*	PURPOSE
A.				
B.				
C.				
D.				
G.				
H.				DISPOSAL

FSIS FORM 10625-1 (10/85) COPY 1 for Lab File; COPY 2 for Headquarters; COPY 3 for Incomplete File

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

11,100.1 | 2-11-86

SUBMISSION OF BLUEPRINTS ON APPLICATION FOR INSPECTION

I. PURPOSE

This Directive provides information to meat and poultry inspection personnel regarding blueprint submittal when making application for inspection.

II. CANCELLATION

MPI Manual, Part 4.

III. REASON FOR ISSUANCE

To replace Part 4 of the MPI Manual.

IV. REFERENCES

Meat and Poultry Inspection Regulations, Parts 304, 305, 307, 308, and Subparts D, E, G and H;
Training Guide - Guideline for Granting Inspection;
AH 570 - Agriculture Handbook - U.S. Inspected Meat and Poultry Packing Plants;
Federal Facility Requirements for Small Existing Plants

V. ABBREVIATIONS AND FORMS

The following will appear in their shortened form in this Directive:

IIC - Inspector in Charge
MPITS - Meat and Poultry Inspection Technical Services
FESD - Facilities, Equipment and Sanitation Division
AH 570 - Agriculture Handbook - U.S. Inspected Meat and Poultry Packing Plants

MP Form 423 - Submission and Approval of Plans and Specifications

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: Facilities, Equipment and Sanitation Division, MPITS

VI. POLICY

When an establishment applies for federal inspection of meat and poultry products, a part of the application process consists of submitting blueprints of the establishment for approval by the Administrator.

VII. PROCEDURES

A. Instructions for processing drawings of establishments:

1. **Drawings** must be in compliance with the Meat inspection Regulations, Parts 304, 307, and 308, and Subparts D (§381.19), G and H, and AH 570. The drawings shall include plot plan, floor plans, plumbing plans, room finish schedule and specifications.

2. **New Construction** or remodeling drawings must be submitted and approval obtained as required in the MPI Regulations in advance of any construction or remodeling. New or remodeled departments should not be used until they comply with approved blueprints. Drawings, accompanied by MP Form 423, must be forwarded through the Area Supervisor or their designee to MPITS/FESD. The Area Supervisor will assure that all drawings comply with instructions in the MPI Regulations and that the drawings are fully informative and comply with inspection requirements.

3. **If Changes** are necessary to comply with department requirements for proper processing of prints by MPITS/FESD, the drawings will be returned to the establishment for correction. The Area Supervisor or their designee will forward the drawings with comments and recommendations to MPITS/FESD for final review. **EXCEPTION** : All blueprints for **import facilities** will be submitted through the import field office supervisor.

4. **Paster Drawings.** Changes pasted onto drawings (pasters) must be presented with one paster affixed to the most recently approved master drawing. The pasters must not obscure any portion of the drawing not affected by the change. The paster must be prepared to the same scale and have the same color background as the master drawing. After applying approximately three pasters, the master drawing should be replaced by a new drawing.

5. **Obsolete Drawings.** Any approved drawings that are 3 years old and inspection has not yet begun will be considered obsolete. Those obsolete drawings are to be destroyed. The Area Supervisor will notify MPITS/FESD when projects are abandoned or when inspection has been withdrawn.

6. **Yearly Review.** Circuit supervisors and IIC's will review all drawings at least once a year. Drawings, upon completion of the review, will be initialed and dated by the reviewer.

7. **MP Form 423.** When an establishment applies for Federal inspection, MP Form 423 is completed and submitted with blueprints to FESD. Instructions for use and distribution are included on the form. When a proposed change has been completed or within 1 year after approved proposed changes have **not** been completed, the IIC will return Copy #5 of the MP Form 423 to MPITS/FESD for evaluation.

B. Survey of facility by the Area Supervisor or designee to assure conformity with drawings as follows:

1. **Read** the specifications accompanying the drawings before surveying and become familiar with the floor plan, rail heights, type of ventilation, water supply, sewage disposal system, floor drain traps, equipment construction, lighting arrangements, floor, wall, and ceiling finishes and other important features or standards often included only in the specifications.

2. **Survey** proposed plants to determine compliance with approved drawings and specifications, and general readiness for inspection.

3. **Survey** construction at official plants involving plant enlargement or remodeling projects to assure compliance with approved drawings.

4. **Ensure** the following equipment is available for survey: scale ruler, tape measure (preferably metal), light meter, colored pencil for noting deviations on drawings.

5. **Measure** ceiling and rail heights, spacing of intended operations, door widths, spacing of fixed equipment in relation to walls.

6. **Locate** floor drains, floor pitch toward drains, handwashing facilities--hot and cold water, liquid soap dispensers, individual towels, and used towel receptacles--hot and cold water hose connections, and major pieces of equipment. Return product areas, retain cage.

7. **Review** the water system with emphasis on distribution, capacity and ability to deliver hot water at a specific temperature to certain locations.

8. **Examine** the following: ventilation systems in work areas and welfare rooms; the placement of thermometers in hot water lines; facilities for maintaining refrigerated work spaces at temperature designated on drawings or in specifications; lighting systems in ante-mortem, slaughter, and processing areas; and outside premises such as roadways, livestock pens, area around catch basins, etc., to determine that inspection requirements are met.

9. **Examine** employees' welfare facilities and inspectors' offices.

C. Survey Report

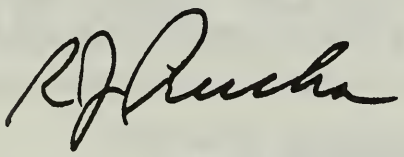
1. **Program Responsibility**

(a) The Area Supervisor will complete a written report and give it to the owner/operator of the establishment, specifying changes and/or additions required to render the facility acceptable. A copy of the report will be forwarded to the Regional Director.

(b) Area Supervisor may accept certain deviations from approved drawings or specifications--slight relocation of a lavatory, hot and cold water hose connections, a piece of equipment provided such deviations do not interfere with inspection and sanitation. Other deviations must be corrected or cleared with MPITS/FESD.

2. **Establishment Responsibility**

(a) When deficiencies are corrected, the owner/operator of the establishment notifies the Area Supervisor and, at that time, requests another survey.



Deputy Administrator
Meat and Poultry Inspection Operations